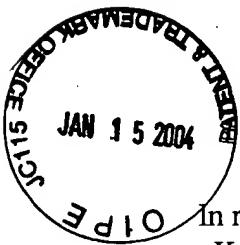


01-20-04

Receipt

EXPRESS MAIL NO.: EL615430864US

DATE MAILED: January 15, 2004



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kurt C. Gish, *et al.*

Application Serial No. 09/976,858

Filed: October 12, 2001

For: **METHODS OF DIAGNOSIS OF  
PROSTATE CANCER,  
COMPOSITIONS, AND  
METHODS OF SCREENING FOR  
MODULATORS OF PROSTATE  
CANCER**

Art Unit: 1642

Examiner: Not Yet Assigned.

Confirmation No.: 2852

Attorney's Docket No:  
05882.0183.NPUS00

**Information Disclosure Statement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed;
  - a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
  - b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - c. Before the mailing date of a first Office Action on the merits;
  - d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

or;

- 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
  - a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure

Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or

- c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
- 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i), and
  - a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- 4. Relevance of the non-English language document(s) is discussed in the present specification.
- 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- 6. A concise explanation of the relevance of the non-English language document(s) appears below:

7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

■ 8. Copies of the documents indicated by a single asterisk were cited by or submitted to the Office in Application No. 09/847,046, filed April 30, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

■ 9. Copies of the documents indicated by two asterisks were cited by or submitted to the Office in Application No. 09/733,288, filed December 8, 2000, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 05882.0183.NPUS00.

Respectfully submitted,

Date: January 15, 2004

  
Albert P. Hallin, (Reg. No. 25,227)  
Robin C. Chiang (Reg. No. 46,619)

HOWREY SIMON ARNOLD & WHITE, LLP  
301 Ravenswood Avenue  
Box 34  
Menlo Park, CA 94025  
(650) 463-8109



## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

## PTO FORM 1449

ATTY. DOCKET NO.

05882.0183.NPUS00

APPLICATION NO.

09/976,858

APPLICANT

Kurt C. Gish, et al.

FILING DATE

October 12, 2001

GROUP

1642

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	CITE NO	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1.	5,514,554	07/1995	Bacus			

## FOREIGN PATENT DOCUMENTS

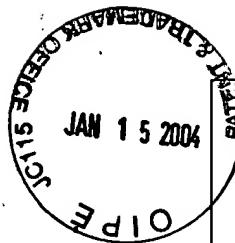
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B1.	WO 98/18945	05/1998	PCT				
	B2.	WO 98/34118	08/1998	PCT				
	B3.	WO 99/23230	05/1999	PCT				
	B4.	WO 99/33869	07/1999	PCT				
	B6.	WO 99/25877	05/1999	PCT				
	B5.	WO 00/08210	02/2000	PCT				

## OTHER REFERENCES

(Including Author, Title, Date, Pertinent Pages, Etc.)

*	C1.	Ahn, et al., "The structural and functional diversity of dystrophin," <i>Nature Genetics</i> , 3(4):283-91 (1993)
*	C2.	Cawthon, et al., "cDNA sequence and genomic structure of EV12B, a gene lying within an intron of the neurofibromatosis type 1 gene," <i>Genomics</i> 9(3):446-60 (1991)
*	C3.	Oshima, et al., Accession No: AK097748 7 (2002)
*	C4.	Kibel, et al. "Loss of heterozygosity at 12P12-13 in primary and metastatic prostate adenocarcinoma," <i>J. Urol.</i> , 164(1): 192-6 (2000)
*	C5.	MPSRCH search report, us-09-847-046-1.mg, pp. 6-7
*	C6.	Lewin, "Genes," John Wiley & Sons, New York, pp. 190-1 (1983)
*	C7.	Mermod, "Enhancer binding factors AP-4 and AP-1 act in concert to activate SV40 late transcription in vitro," <i>Nature</i> 332(6164):557-61 (1988)
**	C8.	Landis, et al., "Cancer statistics 1998," <i>CA Cancer J. Clin.</i> 48(1):6-29 (1998)
**	C9.	Greenlee, et al., "Cancer statistics 2000," <i>CA Cancer J. Clin.</i> 50(1):7-33 (2000)
**	C10.	Nakata, et al., "Trends and characteristics in prostate cancer mortality in Japan," <i>Int. J. Urol.</i> 7(7):254-7 (2000)

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



**LIST OF REFERENCES CITED BY APPLICANT**  
*(Use several sheets if necessary)*

**PTO FORM 1449**

ATTY. DOCKET NO. <b>05882.0183.NPUS00</b>	APPLICATION NO. <b>09/976,858</b>
APPLICANT <b>Kurt C. Gish, et al.</b>	
FILING DATE <b>October 12, 2001</b>	GROUP <b>1642</b>

**	C11.	Majeed, <i>et al.</i> , "Trends in prostate cancer incidence, mortality and survival in England and Wales 1971-1998," <i>BJU Int.</i> 85(9):1058-62 (2000)
**	C12.	Nowroozi, <i>et al.</i> , "The Current Status of Gene Therapy for Prostate Cancer," <i>Cancer Control</i> 5(6):522-31.
**	C13.	Panvichian, <i>et al.</i> , "Hormonal and Chemotherapeutic Systemic Therapy for Metastatic Prostate Cancer," <i>Cancer Control</i> 3(6):493-500 (1996)
**	C14.	Rago, <i>et al.</i> , "Management of Hormone-Sensitive and Hormone-Refractory Metastatic Prostate Cancer," <i>Cancer Control</i> 5(6):513-21 (1998)
**	C15.	Nagabhushan, <i>et al.</i> , "CWR22: the first human prostate cancer xenograft with strongly androgen-dependent and relapsed strains both in vivo and in soft agar," <i>Cancer Res.</i> 56(13):3042-6 (1996)
**	C16.	Agus, <i>et al.</i> , "Prostate cancer cell cycle regulators: response to androgen withdrawal and development of androgen independence," <i>J. Natl. Cancer Inst.</i> 91(21):1869-76 (1999)
**	C17.	Bubendorf, L., "Hormone therapy failure in human prostate cancer: analysis by complementary DNA and tissue microarrays," <i>J. Natl. Cancer Inst.</i> 91(20):1758-64 (1999)
**	C18.	Smith, <i>et al.</i> , "Paclitaxel in the treatment of hormone-refractory prostate cancer, <i>Semin Oncol.</i> 26 (1 Suppl 2):109-11 (1999)
**	C19.	Yang, <i>et al.</i> , "Combining SSH and cDNA microarrays for rapid identification of differentially expressed genes," <i>Nucleic Acids Res.</i> 27(6):1517-1523 (1999)
**	C20.	Derisi, <i>et al.</i> , "Use of cDNA microarray to analyse gene expression patterns in human cancer," <i>Nature Genetics</i> 14:457-60 (1996)
**	C21.	Welford, <i>et al.</i> , "Detection of differentially expressed genes in primary tumor tissues using representational differences analysis coupled to microarray hybridization," <i>Nucleic Acids Res.</i> 26(12):3059-65 (1998)
**	C22.	Khan, <i>et al.</i> , "Expression profiling in cancer using cDNA microarrays," <i>Electrophoresis</i> 20:223-9 (1999)
**	C23.	Ross, <i>et al.</i> , "The HER-2/neu oncogene in breast cancer: prognostic factor, predictive factor, and target for therapy," <i>Stem Cells</i> 16(6):413-28 (1998)
**	C24.	Maloney, <i>et al.</i> , "IDE-C2B8 (Rituximab) anti-CD20 monoclonal antibody therapy in patients with relapsed low-grade non-Hodgkin's lymphoma," <i>Blood</i> 90(6):2188-95 (1997)
**	C25.	Leget, <i>et al.</i> , "Use of rituximab, the new FDA-approved antibody,: <i>Curr Opin Oncol.</i> 10(6):548-51 (1998)
**	C26.	Israeli, <i>et al.</i> , "Molecular cloning of a complementary DNA encoding a prostate-specific membrane antigen," <i>Cancer Res.</i> 53(2):227-30 (1993)
**	C26.	Reiter, <i>et al.</i> , "Prostate stem cell antigen: a cell surface marker overexpressed in prostate cancer," <i>Proc. Natl. Acad. Sci. U. S. A.</i> 95(4):1735-40 (1998)

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

PTO FORM 1449

ATTY. DOCKET NO.	APPLICATION NO.
05882.0183.NPUS00	09/976,858
APPLICANT	
Kurt C. Gish, et al.	
FILING DATE	GROUP
October 12, 2001	1642

**	C27.	Hubert, et al., "STEAP: a prostate-specific cell-surface antigen highly expressed in human prostate tumors," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 96(25):14523-8 (1999)
**	C28.	Carter, et al., "Prostate-specific membrane antigen is a hydrolase with substrate and pharmacologic characteristics of a neuropeptidase," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 93(2):749-53 (1996)
**	C29.	Sodee, et al., "Preliminary imaging results using In-111 labeled CYT-356 (Prostascint) in the detection of recurrent prostate cancer," <i>Clin. Nucl. Med.</i> 21(10):759-67 (1996)
**	C30.	Gregorakis, et al., "Prostate-specific membrane antigen: current and future utility," <i>Semin Urol. Oncol.</i> 16(1):2-12 (1998)
**	C31.	Liu, et al., "Constitutive and antibody-induced internalization of prostate-specific membrane antigen," <i>Cancer Res.</i> 58(18):4055-60 (1998)
**	C32.	Murphy, et al., "Isolation and characterization of monoclonal antibodies specific for the extracellular domain of prostate specific membrane antigen," <i>J. Urol.</i> 160(6 Pt 2):2396-401 (1998)
**	C33.	Silver, et al., "Prostate-specific membrane antigen expression in normal and malignant human tissue," <i>Clin. Cancer Res.</i> 3(1):81-5 (1997)
**	C34.	Liefers, et al., "Micrometastases and Survival in Stage II Colorectal Cancer," <i>New England J. Med.</i> 339(4):223-8 (1998)
**	C35.	Gu, et al., "Prostate stem cell antigen (PSCA) expression increases with high gleason score, advanced stage and bone metastasis in prostate cancer," <i>Oncogene</i> 19(10):1288-96 (2000)
**	C36	Nagase, et al., "Prediction of the coding sequences of unidentified human genes XVI. The complete sequences of 150 new cDNA clones from brain which code for large proteins in vitro," <i>DNA Res.</i> 7(1):65-73 (2000)

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.